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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,481	02/10/2004	Scott A. Waldman	TJU0016-100/WAL_SCO.008	1053
35148 7590 03/05/2007 COZEN O' CONNOR, P.C.. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			EXAMINER JOYCE, CATHERINE	
			ART UNIT	PAPER NUMBER
			1642	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		03/05/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/775,481	WALDMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Catherine M. Joyce	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

1. Claims 1-131 are pending.
2. Upon review and reconsideration, the restriction requirement mailed September 22, 2006 is withdrawn the restriction requirement set forth below is issued in lieu thereof.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  1. Claims 1-35, 42-51, 66, 68-103, and 110-119 as drawn to a method of treating an individual who has cancer by increasing the number of ST receptor molecules on the surface of the cancer cells in an individual, classified in class 424, subclass 184.1.
  2. Claims 36-41 and 104-109, as drawn to a pharmaceutical composition comprising a sterile, pyrogen free ST receptor ligand, classified in class 530, subclass 300.
  3. Claims 1-35, 52-58, and 120-126, as drawn to a method of imaging a tumor in an individual by increasing the number of ST receptor molecules on the surface of a metastasized colorectal cancer in an individual, classified in class 424, subclass 9:1.
  4. Claims 1-35, 59-60, and 127-128, as drawn to a method of determining whether an individual has cancer, classified in class 424, subclass 9.1.
  5. Claims 1-35, 61-63, 129-131 as drawn to a method of delivering an active compound to a cell in an individual, classified in class 424, subclass 184.1.

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6. Claim 64, 65, 68-103, as drawn to a method of inducing a cytostatic effect in, or inhibiting the proliferation of, a primary or metastasized colorectal, gastric, or esophageal cancer, classified in class 424, subclass 184.1.
7. Claims 67-103, as drawn to a method of inhibiting metastasis of, a primary or metastasized colorectal, gastric, or esophageal cancer, classified in class 424, subclass 184.1.

Claim 1 link(s) inventions 1 and 3-5. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions are distinct, each from the other, because of the following reasons:

The inventions of groups 1 and 3-7 are distinct methods that employ different method steps and reagents in different patient populations. While the searches for the different methods would be overlapping they would not be coextensive. Thus, searching any of groups 1, 3-7 together would pose an undue search burden. The inventions of group 2 is related to the inventions of groups 1 and 3-7 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

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practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process such as affinity chromatography. Thus, searching any of groups 1-7 together would pose an undue search burden.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Further, the following election of species are required if relevant to the elected group.

If applicant elects group 1, 3-7 election of a specific mode of administration for the ST receptor ligand from the following list is required: into the circulatory system, intravenously, intratumorally.

If applicant elects group 1, 3-7 election of a specific ST receptor ligand or binding moiety from the following list is required: an anti-ST receptor antibody; an ST receptor binding peptide.

If a receptor binding peptide above is elected, election of a specific receptor binding peptide from the following list is required: the peptide of SEQ ID NO:2, the peptide of SEQ ID NO:3, the peptide of any one of SEQ ID NOs:5-56.

If Applicant elects group 1, election of a therapeutic agent from the following list is required: chemotherapeutics, toxins, radioactive agents, and radiosensitizing agents.

If applicant elects a therapeutic radioactive agent above, election of a specific radioactive agent from the following list is required:  $^{43}\text{K}$ ,  $^{52}\text{Fe}$ ,  $^{57}\text{Co}$ ,  $^{67}\text{Cu}$ ,  $^{67}\text{Ga}$ ,  $^{68}\text{Ga}$ ,  $^{77}\text{Br}$ ,  $^{81}\text{Rb}$ ,  $^{81}\text{MKr}$ ,  $^{87}\text{MSr}$ ,  $^{99}\text{MTc}$ ,  $^{111}\text{In}$ ,  $^{113}\text{MIn}$ ,  $^{123}\text{I}$ ,  $^{125}\text{I}$ ,  $^{127}\text{CS}$ ,  $^{129}\text{Cs}$ ,  $^{131}\text{I}$ ,  $^{132}\text{I}$ ,  $^{197}\text{Hg}$ ,  $^{203}\text{Pb}$ ,  $^{206}\text{Bi}$ ,  $^{47}\text{Sc}$ ,  $^{67}\text{Cu}$ ,  $^{90}\text{Y}$ ,  $^{109}\text{Pd}$ ,  $^{123}\text{I}$ ,  $^{125}\text{I}$ ,  $^{131}\text{I}$ ,  $^{186}\text{Re}$ ,  $^{188}\text{Re}$ ,  $^{199}\text{Au}$ ,  $^{211}\text{At}$ ,  $^{212}\text{Pb}$ ,  $^{212}\text{B}$ .

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$^{32}\text{P}$  and  $^{33}\text{P}$ ,  $^{71}\text{Ge}$ ,  $^{77}\text{As}$ ,  $^{103}\text{Pb}$ ,  $^{105}\text{Rh}$ ,  $^{111}\text{Ag}$ ,  $^{119}\text{Sb}$ ,  $^{121}\text{Sn}$ ,  $^{131}\text{Cs}$ ,  $^{143}\text{Pr}$ ,  $^{161}\text{Tb}$ ,  $^{177}\text{Lu}$ ,  $^{191}\text{Os}$ ,  $^{193}\text{MPt}$  and  $^{197}\text{Hg}$ .

If a chemotherapeutic, toxin or radiosensitizing therapeutic agent above is elected, election of a specific corresponding agent, if any such corresponding agent, from the following list is required: methotrexate, doxorubicin, daunorubicin, cytosinarabioside, etoposide, 5-4 fluorouracil, melphalan, chlorambucil, cis-platin, vindesine, mitomycin, bleomycin, purothionin, macromomycin, 1,4-benzoquinone derivatives, trenimon, ricin, ricin A chain, Pseudomonas exotoxin, diphtheria toxin, Clostridium perfringens phospholipase C, bovine pancreatic ribonuclease, pokeweed antiviral protein, abrin, abrin A chain, cobra venom factor, gelonin, saporin, modeccin, viscumin, volkensin, nitroimidazole, metronidazole and misonidazole.

If Applicant elects group 3, election of an imaging agent from the following list is required: an imaging agent that is radioactive; an imaging agent that is radiostable.

If an imaging agent that is radioactive is elected, election of a specific radioactive agent from the following list is required:  $^{43}\text{K}$ ,  $^{52}\text{Fe}$ ,  $^{57}\text{Co}$ ,  $^{67}\text{Cu}$ ,  $^{67}\text{Ga}$ ,  $^{68}\text{Ga}$ ,  $^{77}\text{Br}$ ,  $^{81}\text{Rb}$ ,  $^{81}\text{MKr}$ ,  $^{87}\text{MSr}$ ,  $^{99}\text{MTc}$ ,  $^{111}\text{In}$ ,  $^{113}\text{MIn}$ ,  $^{123}\text{I}$ ,  $^{125}\text{I}$ ,  $^{127}\text{CS}$ ,  $^{129}\text{Cs}$ ,  $^{131}\text{I}$ ,  $^{132}\text{I}$ ,  $^{197}\text{Hg}$ ,  $^{203}\text{Pb}$ ,  $^{206}\text{Bi}$ ,  $^{47}\text{Sc}$ ,  $^{67}\text{Cu}$ ,  $^{90}\text{Y}$ ,  $^{109}\text{Pd}$ ,  $^{123}\text{I}$ ,  $^{125}\text{I}$ ,  $^{131}\text{I}$ ,  $^{186}\text{Re}$ ,  $^{188}\text{Re}$ ,  $^{199}\text{Au}$ ,  $^{211}\text{At}$ ,  $^{212}\text{Pb}$ ,  $^{212}\text{B}$ ,  $^{32}\text{P}$  and  $^{33}\text{P}$ ,  $^{71}\text{Ge}$ ,  $^{77}\text{As}$ ,  $^{103}\text{Pb}$ ,  $^{105}\text{Rh}$ ,  $^{111}\text{Ag}$ ,  $^{119}\text{Sb}$ ,  $^{121}\text{Sn}$ ,  $^{131}\text{Cs}$ ,  $^{143}\text{Pr}$ ,  $^{161}\text{Tb}$ ,  $^{177}\text{Lu}$ ,  $^{191}\text{Os}$ ,  $^{193}\text{MPt}$  and  $^{197}\text{Hg}$ .

If Group 6 or 7 is elected, election of cancer from the following list is required: primary colorectal, metastasized colorectal, primary gastric, metastasized gastric, primary esophageal, metastasized esophageal.

If Group 1, 3, or 4 is elected, election of cancer from the following list is required: metastasized colorectal, primary gastric, metastasized gastric, primary esophageal, metastasized esophageal.

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If Group 6 or 7 is elected, election of therapeutic agent from the following list is required: 5-fluorouracil; bleomycin.

If Applicant elects group 1, election of a therapeutic agent from the following list is required: compounds that cause cell death; compounds that inhibit cell division; compounds that induce cell differentiation.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note

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that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached at 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine M. Joyce  
Examiner  
Art Unit 1642

SUSAN J. JOYCE  
PRIMARY EXAMINER

